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PATENT ABSTRACTS OF JAPAN

(11)Publication number:

2000-283977

(43)Date of publication of application: 13.10.2000

(51)Int.CI.

GO1N 33/15

(21)Application number: 11-093651

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(22)Date of filing:

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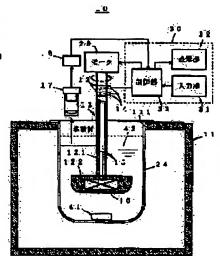
(54) TESTING APPARATUS FOR TABLET ELUTION TEST

31.03.1999

(57)Abstract:

PROBLEM TO BE SOLVED: To accurately measure a temperature of a testing solution used for dissolving a test tablet, and to control the temperature with high responsiveness, without disturbing an agitation condition of the testing solution.

SOLUTION: A control part 33 finds an accurate temperature of a testing solution 42 based on a signal which a heat radiation detector 17 receives a heat radiation (infrared ray) emitted from a liquid face of a testing solution 42 to output, and a current flowing amount to a heater 16 built in a blade body 122 of a paddle 12 is controlled to maintain the temperature within a specified range. Since the paddle 12 is made of a good heat-conductor, heat generated in the heater 16 is transferred quickly to the testing solution 42.



LEGAL STATUS

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[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]

[Date of final disposal for application]

[Patent number]

[Date of registration]

[Number of appeal against examiner's decision of rejection]

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[Date of extinction of right]

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CLAIMS

[Claim(s)]

[Claim 1] The tablet elution—test machine characterized by to have a thermal—radiation detection means output the signal according to the energy of this thermal radiation, and the heating control means which control the calorific value of said heating element based on the output signal of said thermal—radiation detection means in response to the thermal radiation from the oil level of the testing liquid stored by the heating element and said trial container for heating the testing liquid stored by the trial container and said trial container for storing the testing liquid in which a trial tablet is dissolved.

[Claim 2] The tablet elution test machine characterized by providing the following The trial container for storing the testing liquid in which a trial tablet is dissolved A temperature detection means to output the signal according to the temperature of the testing liquid stored by said trial container The churning child for agitating the testing liquid stored by said trial container The heating control means which controls the calorific value of said heating element based on the heating element built in said churning child's churning section, and the output signal of said temperature detection means

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DETAILED DESCRIPTION

[Detailed Description of the Invention]

[0001]

[Field of the Invention] This invention relates to a tablet elution test machine.

[Description of the Prior Art] According to the convention of a Japanese pharmacopoeia, when manufacturing a chemical in the form of a tablet, when immersed into liquid predetermined in the tablet, it is necessary to dissolve into liquid by predetermined time, and a manufacturer needs to check that an active principle is eluted in the liquid. And the practice of the trial for such a check (it is hereafter called a tablet elution test) is also prescribed to the detail by the Japanese pharmacopoeia. For example, Japanese pharmacopoeia General Test Procedures In the 2nd law of an elution test, the convention covering various items, such as a configuration of a container (trial container) of putting in the classes (a presentation, pH, etc.) of solution (testing liquid) in which a trial tablet is dissolved and an amount, and a testing liquid and a dimension, temperature of a testing liquid, and the approaches (the configuration of the churning child who uses for churning, a dimension, a churning child's rotational speed, etc.) of churning of a testing liquid, is seen. Since there is such a fine convention, it is usually that a tablet elution test is performed using the device only for the trials (namely, tablet elution test machine).

[0003] Drawing 2 is drawing showing the rough configuration of the tablet elution test machine used conventionally, and the part is drawn as the vertical cross section. In this tablet elution test machine 20, a water tank 21 is the tank which has the container maintenance opening 211 in the upper part, and the heater 22 and the temperature sensor 23 are arranged in that pars basilaris ossis occipitalis. What was constituted, for example, using a thermocouple, platinum resistance, etc. as a temperature sensor 23 is used. The trial container 24 created according to the convention of a Japanese pharmacopoeia is set to the container maintenance opening 211 of a water tank 21. In order to enable it to observe the dissolution condition of a tablet from outside, as for the trial container 24, considering as glass is common. If set to the container maintenance opening 211 of a water tank 21, the side attachment wall of the trial container 24 will come to the location close to a temperature sensor 23. The churning child 25 made from stainless steel (paddle) who turns the wing object 252 of a pair to hard flow mutually, and fixes and grows into the lower side face of the rod-like axis 251 is inserted in the trial container 24. The upper limit of the axis 251 of a paddle 25 is being fixed to the revolving shaft (not shown) of a motor 26. Out of the water tank 21, it has the control unit 30 which has the input section 31, a display 32, and a control section 33. A control section 33 controls the energization to a heater 22 and a motor 26 based on the signal from the input section 31, and the output signal of a temperature sensor 23.

[0004] The tablet elution test using the tablet elution test machine 20 of <u>drawing 2</u> is performed by the following procedures. First, water 40 is filled in a water tank 21, the trial container 24 is set to the container maintenance opening 211 of a water tank 21, and only the amount of conventions puts in the testing liquid 42 which dissolves the trial tablet 41 in the trial container 24. Next, if a user sends a trial start signal to a control section 33 by operating the input section 31 of a control unit 30 by the predetermined approach, a control section 33 will start the

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energization to a heater 22 and a motor 26. Here, it is determined beforehand that a paddle 25 rotates the amount of energization to a motor 26 at the rate of a convention centering on an axis 251. On the other hand, feedback control of the amount of energization to a heater 22 is carried out by the control section 33 so that the water temperature called for based on the output signal of a temperature sensor 23 may be convention within the limits and may be maintained. Thus, a control section 33 displays the water temperature called for as mentioned above on a display 32, energizing to a heater 22. If it checks that water temperature is convention within the limits, and has been stabilized, a user will feed the trial tablet 41 into the trial container 24. Then, if predetermined time amount passes, a testing liquid 42 will be taken out and the concentration of the active principle eluted in it will be measured. A spectrophotometer is used for measurement of concentration.

[0005] In the above-mentioned tablet elution test machine 20, temporarily, in order to measure the temperature of a testing liquid 42 directly, a temperature sensor 23 shall be contacted to the direct testing liquid 42, as broken-line 23a of <u>drawing 2</u> showed. If it does in this way, since the movement condition of the testing liquid 42 agitated will be disturbed by temperature sensor 23a, the dissolution rate of the trial tablet 41 is affected. In order to avoid such a problem, in the above-mentioned tablet elution test machine 20, the temperature sensor 23 is arranged besides the trial container 24.

[0006]

[Problem(s) to be Solved by the Invention] Based on presumption that the temperature of the water 40 in the water tank 21 called for based on the output signal of a temperature sensor 23 is equal to the temperature of a testing liquid 42, the amount of energization to a heater 22 is controlled by the above-mentioned tablet elution test machine 20. However, since the trial container 24 made in fact with the glass which is an ingredient with low thermal conductivity, and water 40 with large heat capacity exist between a heater 22 and a testing liquid 42, even if the amount of energization to a heater 22 changes, the temperature of a testing liquid 42 cannot be followed immediately at it. Therefore, in the above-mentioned tablet elution test machine 20, exact temperature of each testing liquid 42 at the time cannot be known, but the precision of temperature control cannot but become low. Moreover, if the responsibility of the temperature change of the testing liquid 42 to change of the calorific value of a heater 22 will be low as mentioned above even if the effect by making the direct testing liquid 42 contact can disregard a temperature sensor 23, temperature control cannot be performed in a high precision. Such a problem may be similarly produced with a tablet elution test machine which heats a trial container from outside at a direct heater without water.

[0007] The place which accomplishes this invention in order to solve such a technical problem, and is made into the purpose is to offer the tablet elution test machine which can control by precision higher than before the temperature of the testing liquid used for the dissolution of a trial tablet.

[8000]

[Means for Solving the Problem] The tablet elution test machine concerning the first invention accomplished in order to solve the above-mentioned technical problem. The heating element for heating the testing liquid stored by the trial container and said trial container for storing the testing liquid in which a trial tablet is dissolved, it is characterized by having a thermal radiation detection means to output the signal according to the energy of this thermal radiation in response to the thermal radiation from the oil level of the testing liquid stored by said trial container, and the heating control means which controls the calorific value of said heating element based on the output signal of said thermal radiation detection means.

[0009] Moreover, the tablet elution test machine concerning the second invention accomplished

in order to solve the above-mentioned technical problem A temperature detection means to output the signal according to the temperature of the testing liquid stored by the trial container and said trial container for storing the testing liquid in which a trial tablet is dissolved, It is characterized by having the churning child for agitating the testing liquid stored by said trial container, the heating element built in said churning child's churning section, and the heating control means which controls the calorific value of said heating element based on the output

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signal of said temperature detection means. [0010]

[The gestalt and effect of the invention] of implementation of invention First, the tablet elution test machine concerning the first invention is described. This tablet elution test machine is equipped with a temperature detection means to output the signal according to that energy in response to the thermal radiation from the oil level of a testing liquid. The output signal of a temperature detection means is sent to a heating control means. A heating control means searches for the temperature of a testing liquid based on the received signal, and it carries out feedback control of the calorific value of a heating element so that the temperature may be maintained at convention within the limits. Thus, with the constituted tablet elution test machine, since the temperature of the testing liquid can be measured correctly, without affecting the churning condition of a testing liquid, temperature control (control of the calorific value of a heating means) can be performed in a high precision.

[0011] Next, the tablet elution test machine concerning the second invention is described. This tablet elution test machine is equipped with the heating element built in a churning child's churning section (for example, wing object of the paddle of <u>drawing 2</u>). A churning child's churning section is created with the ingredient (for example, stainless steel) excellent in workability, corrosion resistance, and thermal conductivity. As a heating element, a well-known thing like heating wire or a Peltier device can be used, for example. The heating element is connected with the heating control means through wiring similarly embedded to the churning child. Feedback control of the calorific value of a heating element is carried out so that a heating control means may search for the temperature of a testing liquid based on the output signal of ** and a temperature detection means and may be maintained at the temperature's convention within the limits. Thus, since the heat generated from the heating element is promptly transmitted to a testing liquid in the constituted tablet elution test machine through the churning section created with the ingredient excellent in thermal conductivity, compared with the tablet elution test machine of <u>drawing 2</u>, the responsibility of the temperature change of the testing liquid to change of the calorific value of a heating element is far high.

[0012] In addition, the trial container for storing the testing liquid in which a trial tablet is dissolved, if the technique of two above—mentioned invention is applied to coincidence, A thermal radiation detection means to output the signal according to the energy of this thermal radiation in response to the thermal radiation from the oil level of the testing liquid stored by said trial container, The tablet elution test machine characterized by having the churning child for agitating the testing liquid stored by said trial container, the heating element built in said churning child's churning section, and the heating control means which controls the calorific value of said heating element based on the output signal of said thermal radiation detection means is obtained. Thus, in the constituted tablet elution test machine, since each effect of the invention mentioned above is obtained by coincidence, the precision of the temperature control of a testing liquid increases further.

[0013]

[Example] It explains referring to drawing 1 about the example of the tablet elution test machine which applied the technique of the first invention and the second invention to coincidence. In addition, in the following explanation, when the component consider that is the same configuration—wise and functionally with it about each component of the tablet elution test machine of drawing 1 is contained in the conventional tablet elution test machine shown in drawing 2, the same sign as what was used by drawing 2 is given to the component, and the explanation is omitted suitably.

[0014] <u>Drawing 1</u> is drawing showing the rough configuration of the tablet elution test machine of this example, and the part is drawn as the vertical cross section. This tablet elution test machine 10 is equipped with the paddle 12 inserted in the trial container 24 set to the container maintenance opening 111 of the heat insulation tub 11 from the top. This paddle 12 is a product made from stainless steel, fixes a wing object 122 to the lower limit of the rod-like axis 121, and grows into it. The annular energization terminal 13 of the pair which consists of a conductive ingredient is estranged and formed in the up side face of the axis 121 of a paddle 12. These

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energization terminals 13 are electrically connected with the control section 33 of a control unit 30 through the brush 14 of the pair which consists of a conductive ingredient. On the other hand, the interior of an axis 121 serves as a cavity, and the lead wire 15 of a pair is arranged there. The upper limit of the lead wire 15 of this pair is connected to the energization terminal 13 of the top Norikazu pair in the interior of an axis 121, respectively. On the other hand, the heating elements 16, such as a Peltier device, are built in the wing object 122 of a paddle 12, and the lewer limit of lead wire 15 is connected here.

[0015] Moreover, the tablet elution test machine 10 of <u>drawing 1</u> has the thermal radiation detector 17 arranged in the location which can receive the thermal radiation emitted from the oil level of the testing liquid 42 stored by the trial container 24. The output terminal of this thermal radiation detector 17 is connected to the control section 33 of a control unit 30 through amplifier 18. In addition, it is desirable to use what has high sensibility especially in the wavelength field (near-infrared or infrared region) of the thermal radiation which comes out of the body which has the temperature near human being's temperature as a thermal radiation detector 17. Such a thermal radiation detector can be constituted using a plumbous sulfide (PbS) component, a pyroelectric sensing element, etc. from which electric resistance changes, if infrared radiation is received.

[0016] The tablet elution test using the tablet elution test machine 10 of drawing 1 is performed by the following procedures. First, only the amount of conventions puts in the testing liquid 42 which dissolves the trial tablet 41 in the trial container 24 set to the container maintenance opening 111 of the heat insulation tub 11. Next, if a user sends a trial start signal to a control section 33 by operating the input section 31 of a control unit 30 by the predetermined approach, a control section 33 will start the energization to a heating element 16 and a motor 26. It is determined beforehand that a paddle 12 rotates the amount of energization to a motor 26 at the rate of a convention centering on an axis 121. In addition, since the brush station which a brush 14 is contacted for the rotating annular energization terminal 13, and grows into it with an axis 121 was established on the energization path, even if an axis 121 rotates as mentioned above, the lead wire 15 of the axis 121 interior is not twisted. Feedback control of the amount of energization to a heating element 16 is carried out by the control section 33 so that the solution temperature of the testing liquid 42 called for based on the output signal of the thermal radiation detector 17 may be convention within the limits and may be maintained. Thus, a control section 33 displays the solution temperature called for as mentioned above on a display, energizing to a heating element 16. If it checks that solution temperature is convention within the limits, and has been stabilized, a user will feed the trial tablet 41 into the trial container 24. Then, if predetermined time amount passes, a testing liquid 42 will be taken out and the concentration of the active principle eluted in it will be measured.

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DESCRIPTION OF DRAWINGS

[Brief Description of the Drawings]

[Drawing 1] Drawing showing the rough configuration of the tablet elution test machine concerning this invention.

[Drawing 2] Drawing showing the rough configuration of the tablet elution test machine used conventionally.

[Description of Notations]

10 20 - Tablet elution test machine

12 - Paddle

16 — Heating element

17 - Thermal radiation detector

24 - Trial container

30 -- Control unit

41 - Trial tablet

42 - Testing liquid

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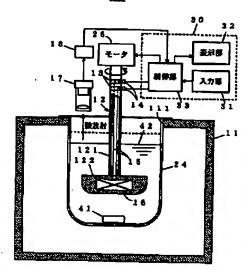
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DRAWINGS

[Drawing 1]

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[Drawing 2]

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